

REMARKS/ARGUMENTS

Reconsideration of the captioned application in view of the foregoing amendments and following remarks is respectfully requested.

A Petition to Extend Time to respond to the pending Office Action by three months is enclosed.

Claims 1-17 are pending and under consideration.

Claims 1-17 are rejected under 35 USC §112, first paragraph as the specification while “enabling for treatment of the symptoms of bipolar disorder does not [allegedly] reasonably provide enablement for preventing bipolar disorder”.

This rejection is obviated by amendment of claim 1.

Applicants submit that the specification is enabling for the full scope of original claim 1.

Nonetheless, to advance prosecution, applicants have amended claim 1 to delete the term “preventing”.

Claims 1-17 are rejected under 35 USC§112, first paragraph as while the specification is “enabling for treatment of the symptoms of a bipolar disorder in a subject, it [allegedly] does not reasonably provide enablement for treating a bipolar disorder”. This rejection is respectfully traversed.

Applicants submit that the specification more than adequately teaches one skilled in the art how to make and use the claimed invention. See, for example, page 10, lines 21-25, which teaches how to make the compounds of the claimed method and page 11, lines 2-6, through page 12, which teach how to use the compounds of formula I for the claimed method. Contrary to the assertions in the Office Action, it is not required under 35 USC §112, first paragraph that applicants specify how a compound “acts”.

Applicants respectfully submit that the burden is on the Patent Office to come forward with evidence to support a rejection of lack of enablement. As the CCPA stated in In re Marzocchi, 169 USPQ 367, 370 (CCPA 1971);

It is incumbent upon the Patent Office, whenever a rejection on this basis [assertion of lack of enablement] to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with

acceptable evidence or reasoning which is inconsistent with the contested statement. (emphasis added)

Contrary to the assertions in the Office Action, no acceptable evidence, as required under Marazocchi, has been presented to refute applicants' position that the specification does just that –enables one skilled in the art to practice the invention. Allegations that the specification is not enabling must be supported "by factual evidence or reasoning substantiating [the] doubt so expressed. [M]ere speculative, factually unsupported allegation[s]. . . cannot negate appellants' assertion that their invention is operative in the broad aspect as claimed." (emphasis added) Ex parte Kronenthal, Appeal No. 562-14, board of Appeals, page 2. Indeed, "no persuasive reasons has been given [in the action] why the specification does not realistically enable, one skilled in the art to practice the invention, as broadly as it is claimed." In re Bowen 181 USPQ 4, 51-52 (CCPA 1974).

The Office Action merely asserts that the claimed treatment of a bipolar disorder is "likely" "unsuccessful".

As shown above, Applicants submit that the claims meet the requirements of 35 USC §112, first paragraph. Thus, Applicants request that the rejection under 35 USC §112, first paragraph, be withdrawn.

Claims 1-17 are rejected under 35 USC §103(a) as allegedly unpatentable over Choi et al. US Patent 6,103,759 in view of Post et al. This rejection is respectfully traversed.

As recognized in the Office Action under reply, Choi nowhere teaches or suggests the use of the claimed compounds for the treatment of bipolar disorder.

In recognition of this deficiency, Post is relied on in the Office Action for teaching that "anticonvulsants have moved into an important position...in the treatment of bipolar illness".

Applicants respectfully submit that to support a combination rejection under §103, not only must the prior art suggest making the claimed invention to one skilled in the art, the prior art must also provide a reasonable expectation of success to one skilled in the art. Both suggestion and expectation must be found in the prior art, not in the Applicants' disclosure. According to the CAFC in In re Vaeck, 20 USPQ2d 1438 (CAFC 1991), what must be considered is:

- (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed

process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success... [citations omitted]... Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the Applicant's disclosure." (at 1442).

Applicants respectfully submit that neither the suggestion nor the reasonable expectation of success are present in the prior art.

Arguably, at most, the cited prior art may be an invitation to experiment. This, however, is not a proper standard for a prior art rejection.

Thus, based on the foregoing, Applicants submit that the claimed invention is patentable over U.S. Patent 6,103,759, in view of Post.

Accordingly, Applicants request that the rejection under 35 USC §103(a) be withdrawn.

Applicants respectfully request an allowance and notice of same.

Respectfully submitted,

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